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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,195	04/22/2004	Marcia Buiser	01194-459001	7713
26161	7590	10/09/2008		
FISH & RICHARDSON PC			EXAMINER	
P.O. BOX 1022			SCHLIENTZ, LEAH H	
MINNEAPOLIS, MN 55440-1022				
			ART UNIT	PAPER NUMBER
			1618	
			NOTIFICATION DATE	DELIVERY MODE
			10/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/830,195

Applicant(s)

BUISE ET AL.

Examiner

Leah Schlientz

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-17, 19-31, 49-54 and 56-59 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-15, 17, 19-31, 49-54 and 56-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 4/4/2008, in reply to the Office Action mailed 1/11/2008 is acknowledged and has been entered. Claims 1-4, 6-17, 19-31, 49-54 and 56-69 are pending, of which claim 16 is withdrawn from consideration at this time as being drawn to a non-elected invention. Claim 1 has been amended. Claims 1-4, 6-15, 17, 19-31, 49-54 and 56-69 are readable upon the elected invention and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments, see pages 8 – 11 of the Response, with respect to the rejection of claims 1, 2, 8, 9, 15, 17, 19 – 23, 25, 26, 28 – 31 and 49 – 59 under 35 USC 103(a) as being unpatentable over Jacobsen (US 6,530,943) and Greene (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), have been fully considered but they are not persuasive for reasons set forth hereinbelow.

Applicant's arguments, see pages 11 – 12 of the Response, with respect to the rejection of claims 1 – 4, 6 – 15, 17, 19 – 26, 28 – 31 and 49 – 59 under 35 USC 103(a) as being unpatentable over Jacobsen (US 6,530,943) and Greene (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), in further view of Mazzocchi (US 6,605,102),

have been fully considered but they are not persuasive for reasons set forth hereinbelow.

Applicant's arguments, see pages 12 – 13 of the Response, with respect to the rejection of claims 1 – 7, 15, 17, 19, 21, 22, 25 – 31, 49 – 54 and 56 – 59 under 35 U.S.C. 103(a) as being unpatentable over Jacobsen (US 6,530,943) in view of Mangin (WO 01/66016), have been fully considered but they are not persuasive for reasons set forth hereinbelow.

Applicant's arguments, see page 13 of the Response, with respect to the rejection of claims 1 - 4, 6 - 15, 17, 19 - 31 and 49 - 53 under 35 U.S.C. 112, second paragraph, have been fully considered. The rejection has been WITHDRAWN as being overcome by amendment.

Applicant's arguments, see pages 14 – 15 of the Response, with respect to the rejection of claims 1 – 4, 6, 7, 15, 17, 19 – 23, 25 – 31, 49 – 54 and 56 – 59 under 35 U.S.C. 103(a) as being unpatentable over Jacobsen (US 6,530,943) in view of Lanphere *et al.* (US 2003/0185895), have been fully considered but they are not persuasive for reasons set forth hereinbelow.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 8, 9, 15, 17, 19 – 23, 25, 26, 28 – 31, 49 – 54 and 56 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen (US 6,530,943) and Greene (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), for reasons set forth in the Office Action mailed 1/11/2008.

Applicant argues on pages 8 – 11 of the Response that Jacobsen does not disclose how to make his particle chain and that instead Jacobsen only discloses the various shapes of the particle chains and their components. Applicant argues that Jacobsen's particle chain does not include the features of the claimed particles, and that there is no teaching regarding how the particle chain disclosed by Jacobsen could be modified to include the particles disclosed in Smith. Applicant further states that for the prior art to render the subject matter covered by a claim obvious, the prior art must enable one skilled in the art to make and use the subject matter being claimed, and that even if Jacobsen did provide an enabling disclosure for how to make his particle chains, one skilled in the art would not know how to make a chain of the type disclosed by Jacobsen with the particles disclosed by Smith because Smith's particles can only be made with the specific methods Smith taught, and Jacobsen's particles do not have the features of Smith's particles and are not made using Smith's methods.

Applicant further argues that Greene's methods of making his embolic device are not compatible with Smith's methods of making his beads. Applicant contends that Greene's methods involve putting a polymer member in a tubular holder followed by coaxially skewering the polymer member with a filamentous carrier, or disposing a filamentous carrier in a mold followed by transferring polymer under pressure into the mold, and that in contrast, Smith makes his particles by spraying droplets of polymer solution into a precipitation bath and drying the droplets to form individual beads. Applicant asserts that one would not have had a reasonable expectation of success in trying to make Smith's particles using Greene's methods that include coaxially skewering a polymer member with filamentous carrier, or disposing a filamentous carrier in a mold followed by transferring polymer under pressure into the mold, and that it would not have been obvious to one skilled in the art to combine Green and Smith to provide Greene's particle chain with Smith's particles.

This is not found to be persuasive. With regard to Applicant's argument that Jacobsen does not teach how to make his particle chain and that even if Jacobsen did provide an enabling disclosure for how to make his particle chains, one skilled in the art would not know how to make a chain of the type disclosed by Jacobsen with the particles disclosed by Smith because Smith's particles can only be made with the specific methods Smith taught, and Jacobsen's particles do not have the features of Smith's particles and are not made using Smith's methods, the examiner repeats the position that prior art is presumed to be operable/enabling per MPEP 2121, as well as that under 35 U.S.C. 282, a patent shall be presumed valid (i.e. and thus is presumed to

meet the enablement requirement). With regard to Applicant's argument that Jacobsen's particles do not have the features of Smith's particles, both Jacobsen and Smith teach porous particles. It is further noted that the instant claims are composition claims, not method of making claims. In response to Applicant's argument that one would not have had a reasonable expectation of success in trying to make Smith's particles using Greene's methods that include coaxially skewering a polymer member with filamentous carrier, or disposing a filamentous carrier in a mold followed by transferring polymer under pressure into the mold, this is not found to be persuasive because one would not necessarily have to make Smith's particles using Greene's methods. For example, one could first prepare Smith's particles, then skewer then onto a filamentous carrier, as in Greene. Furthermore, see MPEP 2145 (III) regarding arguing that prior art devices are not physically combinable. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."); and *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973) ("Combining the teachings of references does not involve an ability to combine their specific structures.").

Claims 1 – 4, 6 – 15, 17, 19 – 26, 28 – 31, 49 – 54 and 56 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen (US 6,530,943) and Greene (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), in further view of Mazzocchi (US 6,605,102), for reasons set forth in the Office Action mailed 1/11/2008.

Applicant argues on pages 11 – 12 of the Response that, for reasons noted above, the combination of Jacobsen and Greene, in view of Smith does not render obvious the claimed subject matter, and that Mazzocchi does not cure the deficiencies of these references.

This is found non-persuasive for reasons set forth above. The Mazzocchi reference is included to address that the claimed aspect ratios are known in the art to be desirable in an embolic device.

Claims 1 – 7, 15, 17, 19, 21, 22, 25 – 31, 49 – 54 and 56 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen (US 6,530,943) in view of Mangin (WO 01/66016), for reasons set forth in the Office Action mailed 1/11/2008.

Applicant argues on pages 12 – 13 of the Response that, as explained above, Jacobsen does not teach how to make his particle chain. Applicant contends that Mangin certainly does not explicitly or inherently disclose an embolic particle having an interior region with pores having a mean size and a surface region having pores with a mean size, the pores of the interior region being greater than the mean size of the pores of the surface region. Applicant argues that Mangin's Figure B is a cross-sectional view of his particles that includes a one dimensional circumference over a two dimensional

circular area representing one cross-section of the particle. Applicant contends that "interior region" of a particle is three dimensional and "surface region" is two or three dimensional and therefore to obtain features of the surface and interior regions of a particle, more than one cross-sectional view of the particle is required. Applicant argues that to strictly analyze the distribution of pore sizes in Magin's particles, infinite numbers of cross-sectional views as shown in Mangin's Figure B are needed.

This is not found to be persuasive. A single figure depicting a cross-section of a particle can be sufficient to demonstrate pore size distribution. This interpretation is supported by the instant specification, which shows only a cartoon of a single cross section, see Figure 5 of the instant Application.

Claims 1 – 4, 6, 7, 15, 17, 19 – 23, 25 – 31, 49 – 54 and 56 - 59 are rejected under 35 U.S.C. 103(a) as being obvious over Jacobsen *et al.* (US 6,530,934) in view of Lanphere *et al.* (US 2003/0185895), for reasons set forth in the Office Action mailed 1/11/2008.

Applicant argues on pages 14 – 15 of the Response that, as noted above, Jacobsen does not disclose or render obvious the features of the claims, and that Lanphere does not cure the deficiencies of Jacobsen. Applicant contends that nowhere does Lanphere disclose or render obvious particle chains that include particles, at least one of the particles having the claimed pore size distribution. Applicant argues that even if one skilled in the art would have somehow wanted to combine the references, that person would not have been able to make the particle chains covered by the claims

because neither Jacobsen nor Lanphere teach how to make such particle chains. Applicant asserts that Jacobsen's particles in his particle chain do not include the features of Lanphere's particles.

This is not found to be persuasive. Both Jacobsen and Lanphere teach porous particles. It is further noted that the instant claims are composition claims, not method of making claims. Furthermore, see MPEP 2145 (III) regarding arguing that prior art devices are not physically combinable. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."); and *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973) ("Combining the teachings of references does not involve an ability to combine their specific structures.").

Conclusion

No claims are allowed at this time.

Although Applicant's arguments as set forth in the aforementioned Response have been fully considered, they are deemed unpersuasive. Accordingly, THIS

ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS